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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/600,990

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Emily F. Hamilton

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EXAMINER

PANI, JOHN

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

11/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/600,990	Applicant(s) HAMILTON, EMILY F.	
	Examiner JOHN PANI	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2008 and 15 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-61 and 77-96 is/are pending in the application.
- 4a) Of the above claim(s) 59-61 and 84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-58, 77-83, and 85-96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Species A (measurement of uterine cervix ripeness) in the reply filed on 7/15/2008 is acknowledged. The traversal is on the ground(s) that a search burden has not been established. This is not found persuasive because the species require searching in different classifications and/or with different search strings, and in addition, prior art applicable to one of the species would not likely be applicable to the other species.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 49-51, 53-55, 77-82, 85-89, 91-93, 95, and 96 rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,876,357 to Tomer et al. ("Tomer").

4. Tomer teaches:

In reference to Claims 49-51, 53, 77, 78, 85, 86, 87, and 91

A process for monitoring an obstetrics patient (pregnant woman) during delivery of a baby, said process comprising: a) providing a user interface control (Fig. 3)

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operable by a user, the user interface control allowing the user to input information (at least by attaching sensors 100, 108, 110, 112, 113, etc. to the patient) on a status/measurement of a modifiable health characteristic of the obstetrics patient ("effacement", etc.), the status of the health characteristic being associated with a likelihood that a cesarean delivery will be required for delivery of the baby (see col. 1 lines 18-22); b) accessing a database in response to the user inputting information on the status of the health characteristic via the user interface control, the database mapping either one of different possible statuses of the health characteristic (comparing current labor pattern to expected) or different possible probabilities of the certain outcome to respective actions for reducing the probability that a cesarean delivery will be required for delivery of the baby (see col. 5 line 50 – col. 6 line 3; note that "therapeutic maneuvers" to correct deviations from normal labor would reduce the probability that a cesarean would be required); c) identifying in the database a particular action ("therapeutic maneuvers") for reducing the likelihood that a cesarean delivery will be required for delivery of the baby at least in part on a basis of the information input by the user; and d) conveying data (col. 5 line 67-col. 6 line 1) indicative of the particular action to the user via a display (106).

In reference to Claims 54, 55, 79, and 80

The process of claims 50 and 77 (see above) further comprising processing the information input by the user for deriving the probability/likelihood of the certain outcome associated with the status of the health characteristic (note, the difference between the expected dilation and effacement curve and the actual is a probability/likelihood,

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because as the distance increases, so does the probability/likelihood a cesarean will be necessary), wherein the identification in the database of a particular action for reducing the probability of the certain outcome is based at least in part on both the information input by the user and the derived probability of the certain outcome (the "therapeutic maneuvers" are chosen based on the deviation, which is based on the received data).

In reference to Claims 81, 82, 88, 89, 92, and 93

The process of claims 77, 87, and 91 (see above) wherein the measurement of the particular health characteristic is a measurement of the ripeness of the uterine cervix ("effacement"), the certain outcome being a delivery by cesarean section.

In reference to Claims 95 and 96

A process for monitoring an obstetrics patient during delivery of a baby, said process comprising: a) providing a user interface control (Fig. 3) operable by a user, the user interface control allowing the user to input information on a status of a health characteristic of the obstetrics patient (at least by attaching sensors 100, 108, 110, 112, 113, etc. to the patient); b) processing (col. 5 lines 40-65) the information on the status of the health characteristic to derive a likelihood that a cesarean delivery will be required for delivery of the baby (note, the difference between the expected dilation and effacement curve and the actual is a probability/likelihood, because as the distance increases, so does the probability/likelihood a cesarean will be necessary); c) processing the information (col. 5 line 65- col. 6 line 3) on the status of the health characteristic to derive a particular action ("therapeutic maneuvers") for reducing the likelihood derived at step b) that a cesarean delivery will be required for delivery of the

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baby (note that “therapeutic maneuvers” to correct deviations from normal labor would reduce the probability that a cesarean would be required); d) displaying on a display screen (106): i. first data (see Fig. 4) conveying the likelihood that a cesarean delivery will be required for delivery of the baby; and ii. second data (see col. 5 line 65-col. 6 line 3) conveying the particular action for reducing the likelihood that a cesarean delivery will be required for delivery of the baby; and iii. data related to the status of the health characteristic provided by the user (Fig. 4).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 52, 56-58, 83, 90, and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tomer in view of US Pat. No. 5,947,991 to Cowan (“Cowan”).

In reference to Claims 52, 83, 90, and 94

Tomer teaches the process of claims 51, 82, 89, and 93 (see above), but does not explicitly teach that the particular action identified in the database is for causing the health characteristic to be modified by affecting the ripeness of the cervix such as to reduce the probability that a cesarean will be required. However, Tomer does teach that medical or surgical intervention are often indicated by slow or inadequate cervical ripening (col. 1 lines 18-22). Cowan teaches that inadequate cervical ripening can

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increase the necessity for a cesarean delivery, and further teaches that it is known to administer oxytocin or mechanically induce ripening in order to avoid a surgical delivery (see col. 1 lines 1-30). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the process of Tomer by suggesting induction of cervical ripening as a therapeutic maneuver when the effacement deviates from ideal, because it is obvious to use an art recognized process to obtain a desired result.

In reference to Claims 56-58

Tomer in view of Cowan teaches the process of claim 52 (see above). Tomer further teaches that the measurement of the health characteristic is a measurement of the ripeness ("effacement") of the uterine cervix, the certain outcome being a delivery by cesarean section. Tomer in view of Cowan teaches affecting the ripeness of the cervix (see above).

Response to Arguments

7. Applicant's arguments with respect to claims 49-58, 77-83, 85, and 86-96 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.P./ 11/13/08

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736